

**Butler, Jennie C**

**From:** furyasz@ncaa.org  
**Sent:** Thursday, June 03, 1999 12:08 PM  
**To:** FDADockets@test.oc.fda.gov  
**Subject:** Ephedrine Comments

June 2, 1999

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, Maryland 20852

RE: DOCTD:fr13my99-60

Dear Food and Drug Administration Officials:

I am writing on behalf of the NCAA and its Committee on Competitive Safeguards and Medical Aspects of Sports. The committee is a representative body of professionals from NCAA member colleges and universities, comprised primarily of institutional sports medicine officials and collegiate athletics administrators. The NCAA is an association of over 900 colleges and universities in the U.S. that sponsor intercollegiate athletics competition for their student-athletes.

Through this letter, I would like to respond to the call for public comments on the development of an overall strategy for achieving effective regulation of dietary supplements. Specifically, I will address the use of ephedrine by college student-athletes. The NCAA urges that this supplement be regulated.

The NCAA operates a comprehensive urine drug-testing program. Over 10,000 tests are conducted each year, making the program the largest athletics drug-testing program in the U.S. Student-athletes are tested for substances on a list of banned drug classes. The NCAA drug-testing programs have been operational since 1986 and provide another level of deterrence for student-athletes who may otherwise feel compelled to use banned drugs.

The United States Dietary Supplements Health and Education Act of 1994 has created a number of problems for sport in the U.S. The lack of regulation as a result of the Act allows young people ready access to anabolic agents, stimulants and other potentially harmful substances. A recent laboratory analysis of a supplement product taken by an NCAA student-athlete showed the presence of three banned substances, none of which were listed as ingredients. Although these problems are much broader than ephedrine, we are pleased that the FDA is reviewing ephedrine.

Ephedrine is an NCAA banned substance. It was added to the NCAA list of banned drugs in 1997 after a national study of NCAA student-athletes showed the following regarding the use of ephedrine:

3.5 % of all athletes reported using ephedrine within the previous 12 months.

51% of ephedrine users used ephedrine to improve their athletic performance.

Food and Drug Administration  
June 2, 1999  
Page No. 2

99N-1174

C7

32% used ephedrine more frequently during the competitive season.

Recent cases involving NCAA student-athletes testing positive for ephedrine underscore the following problems:

Consumers are not aware that these supplements contain potent stimulants.

Labeling is poor. In the case of teas, tea boxes may contain information about ingredients, but the tea bags do not.

Products are marketed toward athletes with no warnings about the use of stimulants during exercise, no warnings about the dangers of combining products, and no warnings that using these products may cause a positive urine drug test in sport.

Products often combine ephedrine with caffeine.

Products confuse consumers with inconsistent terminology, e.g. ephedra, ephedrine, ma huang.

The medical community is confused about the differences between ephedrine and pseudoephedrine, a substance contained in many over-the-counter decongestants..

Unregulated supplement products are sold alongside FDA regulated products in pharmacies, misleading the consumer about purity and efficacy.

The NCAA's committee is knowledgeable about the challenges of regulating the supplement industry. It has warned athletes that their use of these products is truly a "buyer beware" situation. Nevertheless, use of supplements is high among student-athletes.

The NCAA remains interested in cooperative educational and regulatory efforts to reduce young people's use of ephedrine and other substances banned in sport. We urge you to adopt a policy regulating ephedrine.

Sincerely,

Frank D. Uryasz  
Director of Sports Sciences

FDU:hmm